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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/462,517 05/18/00 ZUKER

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EXAMINER

HM12/0731

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ART UNIT

PAPER NUMBER

1632

DATE MAILED:

07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/462,517

Applicant(s)

ZUKER ET AL.

Examiner

Quang Nguyen

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to a fly comprising an amino acid mutation in a transducisome protein that prevents functional binding of a signal transduction protein and an isolated polynucleotide comprising a coding region for a transducisome protein with an amino acid mutation in a PDZ domain that prevents functional binding of a signal transduction protein, wherein said amino acid mutation is not a naturally occurring mutation in *inaD*; an isolated cell comprising the a polynucleotide encoding a transducisome protein with an amino acid mutation that prevents functional binding of a signal transduction protein, wherein said amino acid mutation is a naturally occurring mutation of *inaD*, classified in class 800, subclass 13; class 435, subclasses 320.1, 455, 325, for examples.
- II. Claims 9-10, drawn to an isolated protein comprising a polypeptide of SEQ ID NO:1 with an amino acid mutation in a PDZ domain that prevents functional binding of a signal transduction protein, classified in class 530, subclass 350; class 435, subclass 69.1.
- III. Claims 11-13, drawn to a chimeric transducisome protein comprising at least one first PDZ domain that binds a first signal transduction protein and at least one second PDZ domain binds a second signal transduction protein, classified in class 530, subclass 350; class 435, subclass 69.1.

- IV. Claims 14-23 and 28-34, drawn to methods for identifying modulators of signal transduction using a cell-based assay and an isolated, non-naturally occurring cell having recited properties, classified in class 435, subclasses 4, 6, 455, 320.1, 325, for examples.
- V. Claims 24-27, drawn to a screening assay for detecting protein-protein interactions using a recombinant protein comprising at least one PDZ domain, a PDZ binding protein and at least one test chemical, classified in class 435, subclasses 4, 7.2.
- VI. Claims 35-40, drawn to a chemical identified by preventing the binding of a transducisome protein with a signal transduction protein, a pharmaceutical compound comprising the chemical, and methods of treating a transducisome related disease or of modulating a signal transduction in a cell using a chemical to modulate the association of a transducisome and at least one PDZ binding protein, classified in class 514, subclasses 44, 2. Because of the ambiguous nature of "a chemical identified", this group may be subjected to further restriction depending on the nature of the chemical identified and used.

Should Group III is selected, a further election of species is required.

Claims 11, 12 and 13 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named first signal transduction protein listed in the Markush group of claim 12: a kinase, a phosphatase, a GPCR, a tyrosine kinase receptor, a tyrosine

phosphatase receptor, an ion channel, a G-protein, a phospholipase, or a calcium binding protein.

A specifically named second signal transduction protein listed in the Markush group of claim 13: PKC, TRP or PLCbeta.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Group IV is selected, a further election of species is required.

Claims 14-23 and 28-34 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named signal listed in the Markush group of claims 19: a chemical signal found in blood, a chemical signal found in a synaptic cleft, a chemical signal found in interstitial fluid, a chemical signal found in air and light.

A specifically named signal transduction protein listed in the Markush group of claims 20, 32: a kinase, a phosphatase, a GPCR, a tyrosine kinase receptor, a tyrosine phosphatase receptor, an ion channel, a G-protein, a phospholipase, or a calcium binding protein.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Group V is selected, a further election of species is required.

Claims 24-27 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named PDZ binding protein listed in the Markush group of claim 26: a kinase, a phosphatase, a GPCR, a tyrosine kinase receptor, a tyrosine phosphatase receptor, an ion channel, a G-protein, a phospholipase, or a calcium binding protein.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Group VI is selected, a further election of species is required.

Claims 38-39 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named signal transduction listed in the Markush group of claim 39: G-protein coupled, ion channels, kinases and phospholipases.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

Invention I differs from Inventions II and III because the fly and the isolated polynucleotide of Invention I are chemically and structurally distinct from the isolated protein of Invention II and the chimeric transducin protein of Invention III. While the fly can be used in a screening assay of the instant invention, and the polynucleotide can be used as a hybridization probe, the proteins of Inventions II and III can be used to generate antibodies.

Inventions I and IV are mutually exclusive and independent. The fly or the isolated cell of Invention I are not required for methods of identifying modulators of signal transduction of Invention IV, and vice versa. The polynucleotide of Invention I can be used as a hybridization probe or for generating the fly and is not required for the methods of Invention IV.

Inventions I and V are mutually exclusive and independent. The fly, the isolated cell, and the isolated polynucleotide of Invention I are not required for a screening assay to detect protein-protein interactions of Invention V, and vice versa.

Inventions I and VI are mutually exclusive and independent. The fly, the isolated cell, and the isolated polynucleotide of Invention I are not required for methods of treating a transducisome related disease or of modulating a signal transduction in a cell of Invention VI, and vice versa. Additionally, the compositions of Invention I may be chemically or structurally distinct from an "identified chemical" of Invention VI.

Inventions II and III are drawn to distinct products of different structures and properties. The isolated protein comprising a polypeptide of SEQ ID NO:1 of invention II is not the same nor does it possess chimeric properties of the chimeric transducisome protein of Invention III, and vice versa.

Inventions II and IV are mutually exclusive and independent. The isolated protein comprising a polypeptide of SEQ ID NO:1 of invention II is not required for methods of identifying modulators of signal transduction of Invention IV, and vice versa.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In the instant case, the method of Invention V can be used with the chimeric transducisome protein of Invention III.

Inventions II and VI are mutually exclusive and independent. The isolated protein comprising a polypeptide of SEQ ID NO:1 of invention II is not required for methods of treating a transducisome related disease or of modulating a signal transduction in a cell of Invention VI, and vice versa. Additionally, the isolated protein of Invention I may be chemically or structurally distinct from an "identified chemical" of Invention VI.

Inventions III and IV are mutually exclusive and independent. The chimeric transducisome protein of Invention III is not required for methods of identifying modulators of signal transduction of Invention IV, and vice versa.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In the instant case, the method of Invention V can be used with the isolated protein comprising a polypeptide of SEQ ID NO:1 of invention II.

Inventions III and VI are mutually exclusive and independent. The chimeric transducisome protein of Invention III is not required for methods of treating a transducisome related disease or of modulating a signal transduction in a cell of

Invention VI, and vice versa. Additionally, the chimeric transducisome protein of Invention III may be chemically or structurally distinct from an "identified chemical" of Invention VI.

Inventions IV and V are mutually exclusive and independent methods. Invention IV are drawn to methods of identifying modulators of signal transduction using a cell-based assay, whereas Invention V is directed to a screening assay for detecting protein-protein interactions using a recombinant protein. The methods require different starting materials, steps as well as technical considerations.

Inventions IV and VI are mutually exclusive and independent. The methods for identifying modulators of signal transduction using a cell-based assay in Invention IV require different starting materials, steps as well as technical considerations from methods of treating a transducisome related disease or of modulating a signal transduction in a cell in Invention VI.

Inventions V and VI are mutually exclusive and independent. The screening assay for detecting protein-protein interactions of Invention V requires different starting materials, steps, technical consideration as well as intended outcomes from methods of treating a transducisome related disease or of modulating a signal transduction in a cell in Invention VI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Karen Hauda, at (703) 305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Patsy Zimmerman, whose telephone number is (703) 308-0009.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Papers related to this application may be submitted to Group 160 by facsimile transmission. Papers should be faxed to Group 160 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014 or (703) 308-4242.

Quang Nguyen, Ph.D.


**DAVE T. NGUYEN
PRIMARY EXAMINER**